

## REMARKS

Claims 1-20 have been canceled without prejudice. Claims 21, 25 and 27 have been amended to better claim the invention. The amendment to claim 21 is supported by the as-filed Specification at page 10, lines 25-26. Accordingly, none of the amendments made herein constitutes the addition of new matter.

### The Effective Filing Date of Claims 1, 19 and 20

The Patent Office has noted that the previously amended subject matter does not explicitly provide descriptive support from a prior application, but that claims 1 and 19 are entitled to effective filing dates of 2/21/94 and that claim 20 is entitled to an effective filing date of 6/11/99.

The Patent Office has asserted that WO 95/22335 fails to disclose ascorbyl palmitate, lactic acid, citric acid, formic acid, benzoic acid, and tartaric acid and that it discloses only crèmes and ointments with respect to separately disposed sources of nitrite ions and acidifying agents.

### The Rejection under 35 U.S.C. 112, second paragraph

Claims 25 and 27 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully traverse this rejection.

Claim 25 allegedly lacks antecedent basis for "metal alkali nitrite". Claim 25 has been amended for consistency with base claim 21.

Claim 27 is said to be confusing. Applicants have amended claim 27 for improved clarity with respect to % by weight.

The Rejection under 35 U.S.C. 102

Claims 21-27 have been rejected under 35 U.S.C. 102(e) as allegedly anticipated by the Seitz patent (US 6,103,275). Applicants respectfully traverse this rejection.

Seitz is said to disclose a 1.5% sodium nitrite gel and a separate 3.3% ascorbic acid gel, and the combination of the gels to generate NO for topical treatments.

The Examiner has further stated that Applicant's feature of "in an amount sufficient to establish a pH at an environment of use below 4" is noted with respect to the acid component and also noted that 1-10% ascorbic acid meets that feature (claim 27, line 2). It has been stated that because Seitz discloses a 3.3 wt% ascorbic acid in a gel, this amount is sufficient to meet applicant's claim feature. Also, it is alleged that because Seitz's dosage form contains the same exact components as applicant's dosage form, the same properties must necessarily be present, "for topical treatment of a bacterial, viral or fungal infection".

With respect to the pH at an environment of use, this is taught in WO 95/22335 at page 3, lines 21-22. In the lines following 22-24, it is states "preferably the acidifying agent is an organic acid, for example salicylic acid or ascorbic acid." The Seitz reference appears to teach ascorbic acid and its salt and maleic acid. Clearly, the use of organic acids was contemplated as of the 1995 filing date of the PCT application, prior to the filing date of the Seitz patent. The art understands various particular acids that are classified generally as "organic acids" as well as the concentrations of those organic acids that would produce the noted pH of less than 4 at an environment of use.

While the Seitz reference teaches separate gels comprising the acid and the source of nitrite ions, Applicants respectfully note that WO 95/22335 teaches creams or ointments separately containing the acidifying agent and the source of nitrite ions (See page 3, lines 28-33). Clearly, the use of separate compositions to be combined was

contemplated prior to the filing of the Seitz patent although in a somewhat different form (cream or ointment vs. gel).

In view of the foregoing, Applicants respectfully maintain that the present invention as claimed is not anticipated by the cited Seitz reference, and the withdrawal of the rejection is respectfully requested.

#### Conclusion

Applicants respectfully submit that the pending claims are in condition for allowance and early notification thereof is requested.

If, in the interest of expediting prosecution, the Examiner has questions or comments, he is invited to telephone the undersigned at the indicated telephone number.

This Response is accompanied by a Petition for Extension of Time (two months), and payment of the necessary fee (\$225 as required by 37 C.F.R. 1.17). It is believed that this Amendment and accompanying document does not necessitate the payment of any additional fees under 37 C.F.R. 1.16-1.17. If the amount submitted is incorrect, however, please charge any additional fees due pursuant to the foregoing Rules to Deposit Account No. 07-1969.

Respectfully submitted,

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